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Guidance for the Reregistration of Pesticide Products Containing Triphenyltinhydroxide as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

TRIPHENYLTINHYDROXIDE

AS THE ACTIVE INGREDIENT

EPA CASE NUMBER GS280

ENVIRONMENTAL PROTECTION AGENCY
OFFICIE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

SEPTEMBER 1984

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain you product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Union Carbide Agricultural Products Co., Inc v. Ruckelhaus, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of section 3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in the Guidance Document which do not relate to compliance with the section 3(c)(1)(D) provisions and to supplemnet the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration (s).

Registrants are reminded that section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are neede protect man or the environm will these products be subjec to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

II. Regulatory Position and Rationale

A. Introduction

This Chapter describes the regulatory position of the Environmental Protection Agency, hereafter referred to as "the Agency", on all manufacturing-use products (MPs) containing the fungicide triphenyltin hydroxide (TPTH) as the sole active ingredient. The Agency's position is based on an evaluation of all registered uses, and all products containing TPTH. This document also considers labeling requirements, tolerances, "Special Local Needs" (registrations authorized by Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)), as well as Federal registrations granted or pending under Section 3 of the FIFRA. In addition, this document sets forth the data requirements that must be met to register MPs covered by this Standard.

In developing its regulatory position, the Agency determines whether available data indicate that a pesticide has met the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR). Pesticides meeting these criteria are candidates for a Special Review, an intensive risk/benefit analysis which is a modification of the Rebuttable Presumption Against Registration (RPAR) process. The Agency's determination as to whether the criteria have been met and the rationale for any regulatory action are summarized in the regulatory position of this standard.

This document addresses registration requirements for MPs (containing TPTH) and their intermediaries. TPTH MPs that differ appreciably from those described here may require amendments to the standard. Issues involving specific end-use products will not be addressed under this standard, but general labeling requirements for some formulated products will be discussed in Section G.

B. Use Profile

TPTH is a fungicide registered for use on potatoes, sugar beets, peanuts, pecan trees, and carrots, and is registered for use as a spider mite suppressant on peanuts. TPTH is also registered for use on tobacco, and as an industrial preservative, but is no longer marketed for these two uses. TPTH is currently being tested (under an Experimental Use Permit) as an active ingredient in a marine antifouling paint. As of May 1984 petitions were pending for rice and soybean tolerances.

About 82% of the domestic use of TPTH is on pecans, where it is used to control a number of foliar diseases. TPTH is applied 6 to 10 times annually, on pecan trees, starting at the budbreak stage (pre-pollination) and continuing to just before the shuck split stage at 14 to 21 day intervals. Ground or aerial equipment may be used.

For control of early leafspot and mites on peanuts, TPTH is applied when symptoms of the target infestations occur, usually 25 to 60 days after planting. Applications may continue at 7 to 14 day intervals until 2 to 3 weeks prior to harvest. Overall, 5 to 10 applications may be made per season depending on weather conditions, type and variety of peanuts, amount of irrigation, and other factors. Applications can be made using ground equipment, irrigation systems, or by aerial means.

For control of late blight in potatoes, TPTH is applied up to 10 or 12 times at 5 to 10 day intervals. For control of early blight in the Northwest, 3 to 4 applications may be required on irrigated potatoes. In the Northeast, late-season applications for late blight also control early blight. TPTH is applied to potatoes using ground, aerial, or sprinkler irrigation equipment.

Use on carrots and sugarbeets is minor. On carrots, 1 to 4 applications may be required at 7 to 14 day intervals for adequate disease control. Applications can be made using ground, aerial, or irrigation equipment. In Idaho, 1 to 3 applications may be needed on sugarbeets under furrow irrigation, with more required under sprinkler irrigation.

TPTH formulations include a 47.5% wettable powder, 19.7 and 40% flowable, and 95 and 96% technical solids for industrial use. TPTH is applied with aerial, ground, or sprinkler irrigation equipment at rates of from 1.5 to 12 ounces of active ingredient per acre. The 47.5% wettable formulation is available in water soluble bags that may be added directly to the spray tank.

C. Background

Triphenyltin hydroxide, a member of the organotin family, is commonly referred to by the acronym TPTH. TPTH is also known as fentin hydroxide, (British Standards Institution, International Standards Organization), and as hydroxytriphenyltin. The Chemical Abstracts Service (CAS) number is 76-87-9, and the EPA chemical code number (also known as the Shaughnessy number) is 083601. TPTH is marketed under such names as "Du-ter®", "Duter®", "Haitin®", "Flo-Tin®", "Brestan H®", "Suzu H®", "TPTH", "TPTOH", "Tubotin®", "ENT-28009", "Supertin", and "Triple Tin". At present there are 7 federally registered products containing TPTH as the sole active ingredient, 23 state (24(c)) registrations, and two intrastate registrations. One Experimental Use Permit has been issued for use of TPTH as one of two active ingredients in a marine antifouling paint, under the trade name Rabamarine A/F 1000.

TPTH was first developed for agricultural use by the Thompson-Hayward Agriculture and Nutrition Co., but Thompson-Hayward's interests have been purchased by Uniroyal, Inc. Technical TPTH is manufactured in the United States by M & T Chemicals, and in Amsterdam, Holland by Duphar, Inc. The American Hoechst Co. and Uniroyal are currently seeking rice and/or soybean tolerances.

D. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on TPTH, the Agency has made the following determinations:

1. A Special Review of TPTH will be initiated. The Agency will not reregister any current products or register any new uses of TPTH until the special review is completed and the Agency has received a commitment to fulfill all data gaps.

Rationale: The risk criterion set forth in §162.11 has been exceeded, because a study has shown that TPTH produced teratogenic effects at the lowest dose levels tested. Moreover, farm workers may be exposed to concentrations of TPTH which could cause unreasonable adverse health effects. When a Special Review is completed, an assessment of the benefits of TPTH along with the risk analysis will be published in the Federal Register. Publication of that Notice will constitute the Position Document 1 of the Special Review process.

2. Products containing TPTH, including currently registered products, will be registered only under the "Restricted Use" classification.

   Rationale: TPTH has produced teratogenic effects, as noted above. It also has potential to produce immunotoxic and perhaps oncogenic effects, and may inhibit reproduction. TPTH is in Toxicity Category I for inhalation, dermal, and primary eye irritation exposure routes. Use should be limited to properly trained persons.

3. No new permits will be issued for experimental use as anti-fouling agents in paints.

   Rationale: With its high toxicity to aquatic organisms, TPTH poses too great a threat to non-target populations.

4. No new tolerances will be issued until data gaps involving immunotoxicity, reproductive effects, teratology, oncogenicity, inhalation toxicity, and chronic feeding effects are filled and/or problems in the available studies are resolved to the satisfaction of the Agency.

   Rationale: The current data base does not provide sufficient information to adequately safeguard the public from possible dangers if their dietary intake ~~of TPTH~~ were increased by the granting of new tolerances.

5. The tolerances for TPTH in root and tuber vegetable crops, potatoes, sugar beets, carrots, pecans, and peanuts must be revised to include the intermediary degradation products diphenyltin and monophenyltin hydroxides and oxides, once the Agency has received sufficient data to allow this revision. Registrants must submit data that will allow this revision. The tolerances for meat, milk, poultry, and eggs will also be revised, once the Agency has

a method of detection and residue data. The Agency requires this information. If continued registration on tobacco is desired, the registrants must submit data regarding the residues on freshly harvested tobacco. (See Table A for generic data requirements.)

Rationale: The intermediate degradation products named above may be the cause of some of the observed toxic effects of TPTH. There is insufficient data available to categorize them as innocuous.

5. The Agency will require that certain warnings be placed on the labels of all formulated products containing TPTH. (See Section G(2) of the standard for specific labeling requirements.)

Rationale: Because of the high toxicity of TPTH, label warnings are necessary to protect mixers, loaders, applicators, and others who may be exposed.

6. The required label warnings will include a caution against entering treated areas for 24 hours after application. Registrants must submit re-entry data, as noted in the Table A. (See Section G(2) of this standard for specific labeling requirements.)

Rationale: Re-entry data are required because, based on the use patterns and available toxicity data, the criteria for such requirement in §158.140 have been met. The 24-hour re-entry interval required by this standard will be used as an interim precautionary measure until the submission and analysis of the re-entry data.

7. While the data gaps are being filled and the Special Review process is being completed, currently registered manufacturing-use products containing TPTH as the sole active ingredient may be sold, distributed, formulated and used in the United States, subject to the terms and conditions specified in this standard.

Rationale: The criteria for suspension of product registrations have not been met. In addition, with the imposition of restricted use classification and the label changes set forth in Section F and G below, at this time it does not appear that continued use of TPTH during the special review will cause unreasonable adverse effects on the environment. Many data gaps exist, but it is not the Agency's policy to cancel or withhold registration solely because of data gaps. (See Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA.) When the data gaps are filled, and the Special Review process is completed, the Agency will evaluate whether the new data constitute sufficient grounds for initiating suspension or cancellation proceedings.

E. Criteria for Registration Under This Standard

To be covered by this standard, products must:

- be a manufacturing-use product containing TPTH as the sole active ingredient,
- bear required labeling and conform to the product composition, standard, acute toxicity limits, and use pattern requirements listed in Sections G and H of this document.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Applicants for registration under this standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. Acceptable Ranges and Limits

1. Product Composition Standard

Technical grade products must contain at least 95 percent TPTH as the sole active ingredient. Each manufacturing-use product formulation proposed for registration or reregistration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use TPTH products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a different product and will not be registered under this standard.

2. Acute Toxicity Limits

Because of the high acute toxicity classifications, and other potential toxicological effects of subchronic and/or chronic exposure, the Agency will consider registration of products containing TPTH only under restricted use classification. All labels must bear appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing TPTH must be labeled for formulation into end-use products that are to be used for the control of fungus on peanuts, potatoes, pecan trees, sugar beets, carrots, and tobacco, or for the control of spider mites on peanuts. The Fungicide Index for TPTH is attached to this standard as Appendix A.

G. Required Labeling

All technical grade and manufacturing-use products containing TPTH must bear appropriate labeling as specified in 40 CFR §162.10. Other portions of the guidance package contain specific information regarding label requirements. In addition, the following specific labeling requirements apply to technical and manufacturing-use products:

1. Use Pattern Statements

Labels of manufacturing-use products must bear the statement:

"For formulation into end-use fungicide products intended for use on pecan trees, peanuts, carrots, potatoes, sugar beets, and tobacco, or insecticide products intended for use as spider mite suppressants."

Labels of formulated products must bear the statement:

"RESTRICTED USE PESTICIDE: Because of the high acute toxicity of triphenyltin hydroxide, and its potential for creating teratogenic effects, this product may be applied only by certified applicators or persons directly under their supervision."

2. Precautionary Statements

a. Hazards to Humans Statements

Labels of manufacturing-use and formulated end-use products (EUPs) must bear the statements:

"DANGER - Fatal if inhaled. Corrosive, causes irreversible eye damage. May be harmful or fatal if swallowed or absorbed through the skin. Do not get in eyes, or on skin. Do not breathe dust, vapor, or spray mist. When handling either products containing TPTH or spray-dilute mixtures, wear protective clothing (long pants, long sleeve shirt, impermeable gloves, hat, boots, and a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration and the National Institute for Occupational Safety and Health.) When handling the concentrated products, wear a face shield. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse. Do not enter treated areas for at least 24 hours after treatment."; and

"The United States Environmental Protection Agency has determined that triphenyltin hydroxide causes birth defects in laboratory animals. Exposure to triphenyltin hydroxide during pregnancy should be avoided."

The word "POISON" (in red letters) and a skull and crossbones must appear in close proximity to the word "DANGER".

b. Statements of Practical Treatment

Labels of manufacturing-use and EUPs must bear the statements:

"If on skin: Wash with plenty of soap and water."

"If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

"If in eyes: Flush with plenty of water. Call a physician."

"If swallowed: Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Call a physician or Poison Control Center."

c. Environmental Hazard Statement

The following specific statements must appear on the labels of all manufacturing use products:

"This pesticide is toxic to fish and wildlife. Do not discharge into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All labels of EUPs intended for outdoor use must bear this statement:

"This pesticide is toxic to fish and wildlife. Do not apply directly to water or wetlands. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Cover or incorporate spills. Do not contaminate water by cleaning of equipment or disposal of wastes."

d. Disposal Statements

All labels of manufacturing use and EUPs products must bear this statement, under the heading "STORAGE AND DISPOSAL":

"Do not contaminate water, food, or feed by storage or disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The label of all products (except those intended solely for household use) must bear the appropriate container disposal statement. See Appendix IV-5.

The required statements listed in this standard must appear on the labels of all MUPs and EUPs released for shipment after March 30, 1985. After review of data to be submitted under this standard, the Agency may impose additional label requirements.

H. Tolerance Reassessment

Tolerances of 0.05 to 0.10 ppm were established several years ago for residues of TPTH on carrots, sugar beets, pecans, peanuts, potatoes, and in kidney and liver. A tolerance of 0.40 ppm was established for residues on or in peanut hulls. The original Acceptable Daily Intake (ADI) for TPTH has been re-evaluated as part of the pending soybean tolerance petition. The re-evaluation indicated that an ADI could no longer be determined from the available data base and that additional tolerances should not be established until problems related to the chronic feeding, teratology, reproductive and oncogenicity studies and immunotoxicity potential were resolved, and some additional data submitted. To date the problems have not been resolved. There is no valid ADI for TPTH at this time.

Crop group tolerances for the root and tuber vegetable crops and the tree nuts groups are not appropriate at this time, because data are needed on the storage stability, and on residue levels of the di- and monophenyltin oxides and hydroxides in registered crops. Tolerances for meat, milk, poultry, and eggs will be revised when the problems mentioned above have been resolved, and registrants have submitted a method of detection and the appropriate residue data.

The Theoretical Maximum Residue Concentration (TMRC) calculated from existing tolerances is 0.0106 mg/day, assuming a 1.5 kg diet/day. However, the inclusion of the intermediate metabolites would increase the TMRC by an amount that cannot be assessed at this time. The granting of new tolerances would have the same effect. The TMRC will be recalculated when the Agency receives information on the residue levels of di- and monophenyltin oxides and hydroxides in registered crops.

EPA Index of Pesticide Chemicals

TRIPHENYLTIN HYDROXIDE

c083601

TYPE PESTICIDE: Fungicide
FORMULATIONS: Tech (95%, 96%); WP (47.5%); FlC (0.5625 lb/gal or 5.1%, 1.875 lb/gal or 19.7%, 4 lb/gal or 40%, 4 lb/gal or 40.5%)
GENERAL WARNINGS AND LIMITATIONS:
Dosages are expressed in units of active ingredient.
Livestock tolerances:
0.05 ppm (negligible residue) in the kidney and liver of cattle, goats, hogs, horses and sheep.
Definition(s): MAI - multiple active ingredient, ppm - parts per million.

AGRICULTURAL CROPS

General Warnings and limitations: Do not graze dairy or meat animals in treated areas. Do not add surfactant, spreaders or stickers to sprays. Consult a State Cooperative Agricultural Extension Service regarding timing recommendations.
For ground application equipment: Mix with water for a total solution of 10 to 100 gallons per acre.
For aerial application: Mix with water for a total solution of 3 to 20 gallons per acre.
Sprinkler irrigation application: See specific label instructions and and limitations for this type of use.

Site and Pest	Dosages and Formulation	Tolerance, Use, Limitations	
Carrot		0.1 ppm (negligible residue) 14 day preharvest interval through 3.8 ounces per acre for foliar application. Do not use tops as feed for livestock.	/14003AA
Alternaria blight (late blight)	1.9-3.8 oz/A (47.5% WP) (1.875 lb/gal or 19.7% FlC) (4 lb/gal or 40% FlC) (4 lb/gal or 40.5% FlC)	Foliar application. Use lower rate in protective schedules or when disease is light and increase the rate as disease severity increases. The highest rate is used during high infection periods. Begin application 6 weeks after planting or as soon as first signs of disease appears. Continue at 7 day intervals or as needed for control.	FBASAAX
Cercospora leaf spot			FMBCCBM
Peanut		0.05 ppm (negligible residue) in or on peanuts 0.4 ppm in or on peanut hulls 14 day preharvest interval through 3.8 ounces per acre for foliar application. Do not allow hogs to feed on peanuts in treated fields. Hulls from treated peanuts may be used in feed for livestock. Do not use vines as feed. May be applied by ground equipment, by aircraft or through sprinkler irrigation application.	/28015AA

Site and Pest	Dosages and Formulation	Tolerance, Use, Limitations	
Peanut (continued)			
Cercospora leaf spot	2.38-3.8 oz/A (47.5% WP) (4 lb/gal or 40% FlC) (4 lb/gal or 40.5% FlC) or MAI 2.25-3.75 oz/A (0.5625 lb/gal or 5.1% FlC)	Foliar application. Use the lower rate when disease is light, increasing the rate as disease severity increases. Apply for full coverage to foliage. Use lower gallonage in early season when plants are small and increase spray volume as plant size increases. Application should begin approximately 6 weeks after planting, or as first sign of leafspot appears. Spray applications should continue on a 10 to 14 day schedule. or MAI Formulated with sulfur.	FMBCCBM
	2.38-3.8 oz/A (1.875 lb/gal or 19.7% FlC)	Foliar irrigation system application only. Application should begin approximately 6 weeks after planting, or as first sign of leafspot appears. Applications should continue on a 10 to 14 day schedule. Do not mix with emulsifiable concentrate or liquid formulations. See specific label for other instructions and limitations regarding this type of application.	
Pecan		0.05 ppm (negligible residue) Apply through 2.9 pounds per acre for foliar application. Do not apply after shucks have started to open. May be applied in combination with emulsifiable concentrate or wettable powder insecticides.	/03008AA
Brown leaf spot (cercospora) Downy leaf spot (mycosphaerella) Leaf blotch Liver spot (gnomonia) Powdery mildew (microsphaera) Scab (cladosporium) Sooty mold	0.36-0.71 lb/A (47.5% WP) (1.875 lb/gal or 19.7% FlC) (4 lb/gal or 40% FlC) (4 lb/gal or 40.5% FlC)	Delayed dormant and foliar applications. Apply with ground equipment or by aircraft. Make first application at prepollination stage when young leaves are unfolding and second application when small nuts are forming. Repeat at 2 to 4 week intervals as needed. To maintain control, use lower rate for first two applications, or until disease becomes severe, or during dry weather. Use higher rate during wet weather or during severe disease infection periods.	FMBCCBM FMASMCO FCADMCO FMBDGAT FFACMBT FEAJCCV FHAKQBB

EPA Index of Pesticide Chemicals

TRIPHENYLTIN HYDROXIDE

Site and Pest	Dosages and Formulation	Tolerance, Use, Limitations	
Potato		0.05 ppm (negligible residue) 7 day preharvest interval through 4.75 ounces per acre May be applied in combination with emulsifiable concentrate or wettable powder insecticides, however, before using emulsifiable concentrates it is suggested that the mixture be tested for phytotoxic response under actual use conditions.	/14013AA
Early blight (alternaria) Late blight (phytophthora)	2.38-4.75 oz/A (47.5% WP) (4 lb/gal or 40% FlC) (4 lb/gal or 40.5% FlC)	Foliar application. Begin treatment when weather conditions favor disease development and continue on a 7 day schedule. Full coverage of foliage is necessary for best results.	FBAMAAX FBASPCN
Gray mold (botrytis) Early blight (alternaria) Late blight (phytophthora)	2.85-4.75 oz/A (1.875 lb/gal or 19.7% FlC)	Foliar irrigation system application only. Irrigation systems must be equipped with safety valves or other devices to prevent backsiphoning of pesticide into water source. Any irrigation water treated with this chemical should be held on the treated areas until it is absorbed by the soil. It should not be turned into tail water or fed back into the irrigation system. Apply when weather conditions are favorable for disease development and continue at 7 day intervals.	FHADE FBAMAAX FBASPCN
Sugar beet		0.1 ppm (negligible residue) in or on sugar beet roots 14 day preharvest interval through 4.75 ounces per acre. Do not graze dairy or meat animals in the treated areas or feed beet tops to livestock.	/28020AA
Cercospora leaf spot	1.9-4.75 oz/A (47.5% WP) (1.875 lb/gal or 19.7% FlC) (4 lb/gal or 40% FlC) (4 lb/gal or 40.5% FlC)	Foliar application. Apply when leaf spot symptoms appear or when disease occurs in the area and repeat at 10 to 14 day intervals.	FMBCCBM

Site and Pest	Dosages and Formulation	Tolerance, Use, Limitations	
Tobacco		N.F. Do not use in combination with emulsifiable concentrate or oil spray formulations.	/26003AA
Brown spot (alternaria)	3.09-4.51 oz/A or 0.193-0.294 lb/A (47.5% WP)	Use limited to Southeastern United States. Foliar application. Apply in 40 to 60 gallons of water per acre. Apply as a full coverage spray beginning immediately after the first priming (harvest) and repeat immediately after each weekly priming.	FMAJAAX

AERIAL AND TANK MIX APPLICATIONS

Aerial Applications

— Refer to
Agricultural Crops
Carrots, Peanuts, Pecans, Potato, Sugar beets

TRIPHENYLTIN HYDROXIDE

Listing of Registered Pesticide Products by Formulation

95% technical chemical
  triphenyltin hydroxide (083601)
    047916-00037

96% technical chemical
  triphenyltin hydroxide (083601)
    037100-00013

47.5% wettable powder
  triphenyltin hydroxide (083601)
    000400-00160   000400-00161   008340-00015   037100-00012   044215-00074
    047916-00034

5.1% (0.5625 lb/gal) flowable concentrate
  triphenyltin hydroxide (083601) plus sulfur (077501)
  001812-00252

19.7% (1.875 lb/gal) flowable concentrate
  triphenyltin hydroxide (083601)
  000400-00163

40% (4 lb/gal) flowable concentrate
  triphenyltin hydroxide (083601)
  001812-00244   045115-00014   047916-00035   049085-00001

40.5% (4 lb/gal) flowable concentrate
  triphenyltin hydroxide (083601)
  000400-00164

State Label Registrations:

MI Reg. No.
    000148-05843

WI Reg. No.
    000148-05844

EPA Index of Pesticide Chemicals

TRIPHENYLTIN HYDROXIDE

Appendix B

Listing of Registration Numbers by Site:

Carrots
000400-00160 000400-00161 000400-00163 000400-00164 001812-00244 /014003AA
008340-00015 037100-00012 044215-00074 045115-00014 047916-00034
047916-00035 049085-00001

Peanuts
000400-00160 000400-00161 000400-00163 000400-00164 001812-00244 /28015AA
001812-00252 008340-00015 037100-00012 044215-00074 045115-00014
047916-00034 047916-00035

Pecans
000400-00160 000400-00161 000400-00163 000400-00164 001812-00244 /03008AA
008340-00015 037100-00012 044215-00074 045115-00014 047916-00034
047916-00035 049085-00001

Potato
000400-00160 000400-00161 000400-00163 000400-00164 001812-00244 /14013AA
008340-00015 037100-00012 044215-00074 045115-00014 047916-00034
047916-00035 049085-00001

Sugar beet
000400-00160 000400-00161 000400-00163 000400-00164 001812-00244 /28020A
008340-00015 037100-00012 044215-00074 045115-00014 047916-00034
047916-00035 049085-00001

Tobacco
008340-00015 /26003AA

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.120 Product Chemistry				
Product Identity:				
61-1 - Product Indentity & Disclosure of Ingredients	TGAI	Yes	00083551	No
61-2 - Description of the Manufacturing Process	TGAI	Partially	00083551	Yes[3]/
61-3 - Discussion of Formation of Unintentional Ingredients	TGAI	Partially	00083551	Yes[3]/
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Partially	TH - 46946 ELN dtd May 3, 1982 Duphar - 37100-13 dtd May 12, 1982	Yes[4]/
62-2 - Certification of Limits	TGAI	No	—	Yes
62-3 - Analytical Methods and Data for Enforcement of Limits	TGAI	Partially	00030265 00086487	Yes[5]/

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.120 Product Chemistry (continued)				
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00083551	No
63-3 - Physical State	TGAI	Yes	00083551	No
63-4 - Odor	TGAI	Yes	00083551	No
63-6 - Melting Point	TGAI	Yes	00083551	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	--	Yes
63-8 - Solubility	TGAI	Yes	00083551	No
63-9 - Vapor Pressure	PAI	Partially	00083551	Yes[6]/
63-10 - Dissociation constant	TGAI, PAI	No	--	Yes
63-11 - Octanol/water partition coefficient	PAI	Yes	00093704	No

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63-12 - pH	TGAI, PAI	Yes	00083551	No
63-13 - Stability	TGAI	Yes	00083551	No

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient. Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than June 1, 1985 unless otherwise indicated.

3/ Updated information is needed from all manufacturers/registrants.

4/ Updated information giving analyses of five or more representative samples is needed from all manufacturers/registrants.

5/ Validation data is requested from all manufacturers/registrants.

6/ Vapor pressure data in quantitative terms is requested.

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirements	Composition1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes	00030252 00030311 00030253 00086459 00030254 00086493 00030309 00086494 00030310 00124220 (D-2, D-4, D-5)	No
- Livestock	PAIRA and plant metabolites	Yes	00030250 00080381 00030251 00086552 00030313 00086553 00030315 00086554 00030316 00124220 (D-8, D-10, D-11, D-13)	No
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Partially	00029834 00086472 00029835 00086473 00030259 00086534 00030272 00086545 00036021 00086561 00036027 00086569 00036029 00086571 00080387 00086601 00086450 00086603 00086452 00124220 (D-14, D-16 to 18, D-28)	Yes3/
- Animal Residues	TGAI and metabolites	Partially	See plant citations above.	Yes4/

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry (continued)				
171-4 - Storage Stability Data	PAI	No	--	Yes[5]
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
- Crop Group #1 - (Root and Tuber Vegetables Group)				
o Crop 1 (Potatoes)				
-- Crop field trials	TEP	Partially	00086492 00086494	Yes[6]
o Crop 2 (Sugar Beets)				
-- Crop field trials	TEP	Partially	00086560	Yes[6]
o Crop 3 (Carrots)				
-- Crop field trials	TEP	Partially	00086544	Yes[7]
o Leaves of Root and Tuber Vegetables	N/A[8]	--	--	--

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies (continued)				
- Crop Group #2 (Tree Nuts Group)				
o Crop 1 (Pecans)				
-- Crop field trials	TEP	Partially	00086600	Yes[9]
- Individual Crops				
Peanuts -- Crop field trials	TEP	Partially	00080383 00080384 00086556	Yes[10]
Tobacco -- Crop field trials	TEP	No	--	Yes[11]
-- Meat/milk/poultry/eggs	TGAI	Partially	00053415 00080381	Yes[12]

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than June 7, 1985 unless otherwise specified.

3/ All existing tolerances should be altered to include the metabolites di- and monophenyltin hydroxides (or oxides). None of the methods submitted by the registrants is suitable for determination of the collective or separate residues of TPTH and these two degradates in plants. A method for enforcing a tolerance which includes these two degradates is needed.

4/ All existing tolerances should be altered to include the metabolites di- and monophenyltin hydroxides (or oxides). None of the methods submitted by the registrants is suitable for determination of collective or separate residues of TPTH and its metabolites, di- and monophenyltin hydroxides (or oxides) in meat, milk, poultry, and eggs. New methodology must be submitted which includes a base hydrolysis step, which is necessary to free TPTH residues from conjugates in meat, milk, poultry, and eggs. Analytical methodology for poultry and eggs is also needed. A method for enforcing a tolerance which includes these two metabolites is needed.

5/ Data on storage stability of TPTH residues in plant and animals have not been submitted. Although some samples are said to have been stored a -2°C, no information has been furnished on how long these were held in storage before being analyzed, and none to show whether or not residues were stable during storage for an unreasonable length of time (e.g. more than about two months). Data on storage stability must be submitted no later than December 7, 1985.

6/ Data are needed on the storage stability and the data and methodology for residues of di- and monophenyltin hydroxides (or oxides) in potatoes and sugar beets, and of tetraphenyltin as well, in processed commodities from potatoes and sugar beets. Data must be submitted no later than June 7, 1986.

7/ Data on the residue storage stability, and the data and methodology for residues of di- and monophenyltin hydroxides (or oxides) in carrots are needed. Data must be submitted no later than June 7, 1986.

8/ Tolerances established for the root form of the root and tuber vegetables, individually or collectively (in the crop grouping) must be accompanied either by a restriction against the use of the leaves as human food or animal feed (when practical and appropriate) or by residue data on the leaves (again, individually or as representatives of the crop grouping). [Note: These residue data are in anticipation of a tolerance which should not be established at this time.] In the absence of residue data, such restrictions have been made applicable to carrot and sugar beet tops in the present uses of TPTH where the restrictions are practical and appropriate. Restrictions are not needed for carrot tops and the leaves of potatoes because these are neither food nor feed.

9/ Data are needed on the residue storage stability, and the data and methodology for residues of di- and monophenyltin hydroxides (or oxides) in pecans. [Residue data for the representative crops, almonds and English walnuts, would be needed for a crop group tolerance, which should not be established at this time.] Data must be submitted no later than June 7, 1986.

10/ Data and methodology for residues of di- and monophenyltin hydroxides (or oxides) in peanuts will be needed. Data for tetraphenyltin will be needed for commodities processed from peanuts. Data must be submitted no later than June 7, 1986.

11/ The use of TPTH on tobacco does not require a tolerance or an exemption from the requirement of a tolerance, but data are needed to assess the exposure to residues resulting from the use of the pesticide. For continued registration, residue data on green freshly-harvested tobacco will be needed. If residues of TPTH and di- and monophenyltin hydroxide (or oxides) at 0.1 ppm or more are detected, then the pyrolysis products derived from these residues must be characterized. Data must be submitted no later than June 7, 1986.

12/ Information on residue storage stability, and data and methodology for residue of di- and monophenyltin hydroxides (or oxides) will be needed. The method should be revised or a new method developed to include the determination of the forementioned metabolites collectively with TPTH or separately in meat, milk, poultry, and eggs. The new methodology should also include a base hydrolysis step, which is necessary to free TPTH residues from conjugates in meat, milk, poultry, and eggs. The expression of the established tolerance should be changed to include, di- and monophenyltin hydroxide (or oxides) along with parent TPTH. The required information must be submitted no later than June 7, 1986.

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1]	Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Yes	00093875	No
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No	--	Yes
161-3 - On soil	TGAI or PAIRA	A	No	--	Yes
161-4 - In Air	TGAI or PAIRA	N/A[4]	No	--	--
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No	--	Yes[7]
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	--	Yes[7]
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A[5]	No	--	--
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A[5]	No	--	--

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition1/	Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.130 Environmental Fate (continued)					
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	Partially6/	00099673	Yes13/
163-2 - Volatility (Lab)	TEP	N/A4/	-	--	-
163-3 - Volatility (Field)	TEP	N/A4/	-	--	-
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	No	--	Yes7/
164-2 - Aquatic	TEP	N/A5/	-	--	-
164-3 - Forestry	TEP	N/A8/	-	--	-
164-4 - Combination and Tank Mixes		N/A9/	-	--	-
164-5 - Soil, Long-term	TEP	N/A10/	-	--	-

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.130 Environmental Fate (continued)					
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No	--	Yes7/
165-2 - Rotational Crops (Field)	TEP	N/A11/	--	--	--
165-3 - Irrigated Crops	TEP	N/A5/	--	--	--
165-4 - In Fish	TGAI or PAIRA	A,B	No	--	Yes
165-5 - In Aquatic Non-Target Organisms	TEP	N/A5,6/	--	--	--
§158.140 Reentry Protection	TEP	A,B12/	No	--	Yes7/

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor

3/ Unless otherwise specified, data must be submitted no later than June 7, 1985.

4/ No data are required because TPTH has a low vapor pressure and low soil mobility.

5/ No data are required because there are no aquatic uses and no irrigation by furrow.

6/ Mobility tests are required for silt loam and sand to fulfill requirements for un-aged samples; aged samples must also be tested.

7/ Data must be submitted no later than December 7, 1985.

8/ No data are required because there are no forest uses.

9/ This standard addresses only a single ingredient.

10/ Required if total extractable residues exceed 50% of the initial application at the time of next application.

11/ Required when significant residues of concern are detected in the confined study test crops.

12/ An interim 24-hour reentry interval is required unless protective clothing is worn.

13/ Preliminary, incomplete data indicate that the parent compound of TPTH does not leach appreciably; however, the mobility in silt loam and sand, and the mobility of degradates, remains to be tested.

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition1/	Use Patterns2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	All	Yes	00083557	No
81-2 - Acute Dermal Toxicity	TGAI	All	Yes	00083560	No
81-3 - Acute Inhalation Toxicity - Rat	TGAI	All	Yes	00083562	No
81-4 - Primary Eye Irritation	TGAI	All	Yes	00088622	No
81-5 - Primary Dermal Irritation	TGAI	All	Yes	00124210	No
81-6 - Dermal Sensitization	TGAI	All	Partially	00124210	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	N/A6/	N/A	--	No
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent	TGAI	A	Partially	00045837 00086514 00086548 00045831 00065167 00086467	Yes4/
Non-rodent (dog)	TGAI	A	Partially		Yes5/
Non-rodent (guinea pig)	TGAI	A	Yes		No
82-2 - 21-Day Dermal	TGAI	A,IP	No	--	Yes
82-3 - 90-Day Dermal	TGAI	N/A6/	N/A	--	-
82-4 - 90-Day Inhalation	TGAI	A,IP7/	Partially	00124219	Yes8/
82-5 - 90-Day Neurotoxicity-Hen	TGAI	N/A6/	N/A	--	-

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1]	Use Patterns[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - Rodent (rat)	TGAI	A	Partially	00046016 00080390 00080391	Yes[9]
Non-rodent (dog)	TGAI	A	Partially		Yes[9]
83-2 - Oncogenicity Study - Rat	TGAI	A	Partially	00046016 00080390 00125261	Yes[9]
Mouse	TGAI	A	Partially		Yes[9]
83-3 - Teratogenicity - rat	TGAI	A,IP	Partially	00086547 00094903 00094904	Yes[10]
hamster	TGAI	A,IP	Yes		No
83-4 - Reproduction - 2-generation	TGAI	A	Partially	00086548 00086549	Yes[11]
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	All	Yes	00086551	No
84-2 - Chromosomal Aberration	TGAI	All	No	--	Yes[12]
84-2 - Other Genotoxic Effects	TGAI	All	Partially	05016869	Yes[12]
SPECIAL TESTING:					
85-1 - General Metabolism	PAI or PAIRA	A	No	--	Yes[13]
- Immunotoxicity Studies		All	No	--	Yes[14]
- Dermal Penetration		All	No	--	Yes[15]

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

1/ Composition: Material to be tested is technical grade unless otherwise specified in footnotes. PAI= Pure Active Ingredient. PAIRA= Pure Active Ingredient, Radio-labeled.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor; IP = Industrial Preservative.

3/ Unless otherwise specified, data must be submitted no later than June 7, 1985.

4/ Initiation of a chronic feeding study with rodents and submission of an acceptable interim report will eliminate this requirement. Otherwise, data must be submitted no later than February 7, 1986.

5/ The dog 100-day study was done by IBT, and has not been validated. Initiation of a chronic feeding study with dogs and submission of an acceptable interim report will eliminate the requirement for a 90-day study with dogs. Otherwise, data must be submitted no later than February 7, 1986.

6/ Data are not required.

7/ The requirement for a 90-day inhalation study relates to the acute inhalation toxicity of this chemical.

8/ Additional information related to the 90-day inhalation study was requested of the registrant. No reply has been received. The requested data must be submitted by June 7, 1985. If new studies must be run, the results must be submitted by February 7, 1986.

9/ Where the Agency has requested clarification or explanation of a prior study, such information must be provided no later than June, 7 1985. If new studies must be run, the results must be submitted by December 7, 1988.

10/ The Toxicology Branch (Hazard Evaluation Division) is waiting for the registrant to provide an acceptable defense for establishing a NOEL for teratogenic/fetotoxic effects in rat fetuses. Such information must be provided by June 7, 1985. If new studies must be run, the results must be submitted by December 7, 1985. The Agency will also require postnatal teratology study on rats by gavage, a teratology study on rabbits by gavage, and, depending on the results of these two studies and the results of the dermal penetration study, may also require a teratology study using the dermal route of administration. The results of the first two studies must be submitted by December 7, 1985.

11/ Data must be submitted no later than September 7, 1986.

12/ Data must be submitted no later than September 7, 1985.

13/ Data must be submitted no later than March 7, 1986.

14/ Additional data are required to support continued registration of this chemical; data must be submitted no later than January 7, 1986.

15/ Data must be submitted no later than June 7, 1985.

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TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Acute Oral Toxicity	TGAI	A,B	Yes	00125274[4/] 00125274[5/]	No
71-2 - Avian Dietary Toxicity					
Waterfowl	TGAI TEP	A,B A,B	Partially No	00099092[5/]	Yes Yes[6/]
Upland Gamebird	TEP TGAI	A,B A,B	Partially No	00086486[5/]	Reserved[7/] Yes
71-3 - Wild Mammal Toxicity	TGAI	N/A[8/]	--	--	--
71-4 - Avian Reproduction	TGAI	A,B	Partially	00099093[5/] 00086573[5/]	Yes[9/]
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B	No	-	Reserved[10/]
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish Acute Toxicity	TGAI				
Warmwater Fish		A,B	Yes	00086574[5/] GS028026[4/]	No
Coldwater Fish		A,B	Partially	00086574[5/]	Yes
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B	Yes	00125274[4/] GS028026[5/]	No

TABLE A

GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.145 Wildlife and Aquatic Organisms (continued)					
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI				
a. Shrimp		A,B	Partially	00096633[5]	No
b. Marine Fish		A,B	Partially	00096632[5]	No
c. Oyster		A,B	Partially	00096634[5]	No
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI				
a. Fish		A,B	Yes	00125274[4]	No
b. Aquatic Invertebrate		A,B	Yes	00125274[4]	No
72-5 - Fish - Life-Cycle	TGAI	A,B	No		Reserved[11]
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	N/A[8]	--	--	--
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B	Partially	00086578[5] 00086579[5] 00086581[5]	Reserved[11]

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

§158.145 Wildlife And Aquatic Organisms (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor

3/ Unless otherwise specified, data must be submitted no later than June 7, 1985.

4/ Study fulfills Guideline requirements.

5/ Study must be combined with other studies to fulfill Guideline requirements.

6/ Avian dietary study on waterfowl with formulated product is required because when the technical product was used, the test birds would not eat the test diet in sufficient quantities to produce a valid test result. Apparently the technical material is extremely unpalatable.

7/ Reserved pending avian dietary results from test on technical.

8/ Not applicable at this time.

9/ Avian reproduction studies are required because repeat applications are allowed on all uses and half-life on soil is over 180 days. The results of this study must be submitted no later than June 7, 1986.

10/ Reserved pending results from avian dietary reproduction tests and pertinent environmental fate studies.

11/ Reserved pending results from acute coldwater fish test and pertinent environmental fate studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING -					
Pollinators:					
141-1 - Honey bee acute contact toxicity	TGAI	A,B	Yes	00018842	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	No	-	No4/
141-4 - Honey bee subacute feeding study	[Reserved]5/				
141-5 - Field testing for pollinators	TEP	A,B	No	-	No4/

TABLE A
GENERIC DATA REQUIREMENTS FOR TPTH

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	[Reserved]6/				
142-2 - Aquatic insect life-cycle study	[Reserved]6/				
142-3 - Simulated or actual field testing for aquatic insects	[Reserved]6/				
143-1- thru 143-3 NONTARGET INSECT TESTING PREDATORS AND PARASITES	[Reserved]6/				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use pattern codes are as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted no later than June 7, 1985.

4/ Because acute contact test showed low toxicity to honey bees, no further testing is required.

5/ Reserved pending development of test methodology.

6/ Reserved pending Agency decision as to whether the data requirement should be established.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This Section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TPTH

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry				
Product Identity				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	00083551	No
61-2 - Description of the Manufacturing Process	MP	Partially	00083551	Yes[3]
61-3 - Discussion of Formation of Unintentional Ingredients	MP	Partially	00083551	Yes[3]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	MP	Partially	00083551	Yes[3]
62-2 - Certification of Limits	MP	No	—	Yes
62-3 - Analytical Methods and Data for Enforcement of Limits	MP	Partially	00030265 00086487	Yes[4]

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TPTH

Data Requirement	Composition1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	00083551	No
63-3 - Physical State	MP	Yes	00083551	No
63-4 - Odor	MP	Yes	00083551	No
63-7 - Density, Bulk Density, or Specific Gravity	MP	No	--	Yes
63-12 - pH	MP	Yes	00083551	No
63-14 - Oxidizing/Reducing Action	MP	No	--	Yes
63-15 - Flammability	MP (for combustible liquid only)	N/A	--	No
63-16 - Explodability	MP	No	--	Yes
63-17 - Storage stability	MP	No	--	Yes
63-18 - Viscosity	MP	N/A	--	No
63-19 - Miscibility	MP (for emulsifiable liquid products)	N/A	--	No

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TPTH

Data Requirement	Composition1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.120 Product Chemistry (continued)				
63-20 - Corrosion	MP	No	--	Yes

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than June 7, 1985 unless otherwise specified.

3/ Updated information is needed from all manufacturers/registrants.

4/ Validation data is requested from all manufacturers/registrants.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies to end-use products only to the extent described under Section II of this document. Otherwise, the following information pertains exclusively to manufacturing-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix IV-1 an IV-2], as indicated by the following paragraphs of this chapter of the guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this Section and/or Section II, EPA may issue a notice of intent to cancel the registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR §162.10 (Appendix IV-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix IV-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix IV-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On produ assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix IV-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR §162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

    a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

    b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

    c. A "non-flammable aerosol" is one which meets the following criteria:

        i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

        ii. There is no flash back; and

        iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION: CLASSIFICATION LABELING REQUIREMENTS AND COMPLIANCE SCHEDULE - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to such other restrictions as may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses to be restricted, based either on a previous classification determination made through the optional procedures of 40 CFR 162.30 or based on data already available to the Agency, or (2) indicated certain formulations/uses to be urestricted, based on data already available to the Agency, or (3) reserved any classification decision until appropriate short-term data are submitted. Uses have not been classified for general use at this time because such a decision requires an evaluation of chronic data, most of which has yet to be generated.

The product-specific data required by the standard should be used by each registrant to make a classification determination following the criteria of 40 CFR 162.11(c) (Appendix V-4). The draft label(s) submitted to the Agency as part of your application should reflect this determination, and must be consistent with the terms of 40 CFR 162.10 and this guidance package with respect to label language and format for restricted use products. (No label changes with respect to classification are required for products with unrestricted uses.) The rationale supporting a classification proposal by the registrant that differs from a classification determination found in the Standard should be submitted with your application.

During the Agency's review of your application, your proposed classification determination will be evluated in accordance with the provisions of 162.11(c). You will be notified of the Agency's classification evaluation.

A. Classification Labeling Requirements

1. Unrestricted uses - no label changes with respect to a classification statement are necessary for those formulations/uses that are unrestricted.

2. Restricted uses - Pesticide products bearing directions for use for formulations/uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

    a. Front panel statement of restricted use classification.

        i. At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR 162.10(h)(1)(iv), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

        ii. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the

Certified Applicator's Certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

3. Some But Not all Uses Restricted - If you determine that some uses should be classified RESTRICTED and some uses should be unrestricted, several courses of action detailed below are available:

   i. You may delete all RESTRICTED uses and submit a draft label of the registration of your product to reflect only those uses that are unrestricted.

   ii. Unrestricted uses may appear on a RESTRICTED label, but not vice versa. Therefore, you have the option of using a RESTRICTED USE label bearing all of your directions for use. If you choose this option, you may not distinguish those uses that are not restricted from those which are RESTRICTED.

   iii. You may register two separate products with identical formulations, one containing only unrestricted uses, and the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

1. Unclassified uses - None.

2. Restricted uses - The compliance schedule for restricted use products is as follows:

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after one year from the date of issuance of this Standard, unless such product bears the restricted-use classification. All products still in channels of trade after two years from the date of issuance of this Standard must be labeled for restricted use.

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Product Manager 21 (Henry M. Jacoby)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-1900

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

   d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, the registrant may submit such labeling. (End-use product labeling needs to comply specifically with the instruction in Section II of this guidance document.) The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for stortage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

After the Supreme Court has ruled on the Monsanto Decision, you will be informed as to when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the associated data support information.

APPENDIX II-1

Guide to Use of This Bibliography

1. Content of Bibliography: This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. The bibliography is divided into two sections: (1) citations that contributed information useful to the review of the chemical and that are considered to be part of the data base supporting registrations under the Standard, and (2) citations examined and judged to be inappropriate for use in developing the Standard. This second part of the bibliography exists in the Agency's files and does not accompany this Standard. Interes parties may request a copy from the Agency. Primary sources for studies i this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry: The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries: The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by an eight-character temporary identifier. This is also to be used whenever specific reference is needed.

4. Form of the Entry: In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow;

   a. Author: Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency had shown the first known submitter as author.

   b. Document Date: When the date appears as four digits with no ques marks, the Agency took it directly from the document. When a four digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title: This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

   d. Trailing Parentheses: For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

      (1) Submission Date: Immediately following the word 'received' appears the date of the earliest known submission.

(2) Administrative Number: The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter: The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification: The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second 123456-B; the 26th, 123456-Z, and the 27th 123456-AA.

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00124220 American Hoechst (1983) Summary of Data Presented; (Unpublished studies received Jan 20, 1983 under 3F2823; submitted by American Hoechst; CDL:071370-XA)

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Suprenant, D.C. and G.A. LeBlanc (1982) Acute Toxicity of Triphenyltin Hydroxide (TPTH) to the Water Flea (Daphnia magna). (Unpublished study prepared by EG&G Bionomics, Inc., Wareham, MA for American Hoechst Corp., CDL:249309 Sec. I)

Suprenant, D.C. et al. (1982) The Chronic Toxicity of Triphenyl Hydroxide (TPTH) to the Water Flea (Daphnia magna). (Unpublished report prepared by EG&G Bionomics, Inc. for Thompson-Hayward Agriculture & Nutrition C Inc., CDL:249309 Sec. I)

Wilson, B.F. et al. (1982) The Toxicity of Triphenyltin Hydroxide (TPTH) to the Fathead Minnow (Pimephales promelas) embryos and larvae. (Unpublished study prepared by EG&G Bionomics for Thompson-Hayward Agriculture & Nutrition Co., Inc., CDL:249309 Sec. I-7)

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GS028026 Johnson W.W. and M.T. Finley (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates, U.S. Fish & Wildlife Service Publication No. 137. 98 pp.

APPENDIX II-2

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

APPENDIX II-3

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

Appendix III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.______________ Guidance Document for________________________

Date________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by: Citing MRID#	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated fo each active ingredient shall be lowest percentage which ma present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 20	14	10
Over 20	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

	Points	
of label front panel in square inches	Required signal word, all capitals	"Keep out of reach of Children"
d under	6	6
e 5 to 10	10	6
e 10 to 15	12	8
e 15 to 20	14	10
20	16	12

2) *Other required warnings and pre- itionary statements.* The warnings 1 precautionary statements as re- ired below shall appear together on label under the general heading recautionary Statements" and der appropriate subheadings of azard to Humans and Domestic Ani- ls," "Environmental Hazard" and hysical or Chemical Hazard."

i) *Hazard to humans and domestic imals.* (A) Where a hazard exists to mans or domestic animals, precau- nary statements are required indi- ing the particular hazard, the ite(s) of exposure and the precau- ns to be taken to avoid accident, ury or damage. The precautionary agraph shall be immediately pre- ied by the appropriate hazard signal rd.

B) The following table depicts typi- precautionary statements. These tements must be modified or ex- ided to reflect specific hazards.

nts by toxicity category

Skin and eye local effects
Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
[No precautionary statements required.]

zard and the appropriate precau- ns to avoid potential accident, ury or damage. Examples of the zard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F, if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of applicatio example the crops, animals, objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

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der the heading "Directions
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use classification, the state-
t is a violation of Federal law
his product in a manner incon-
with its labeling."

he site(s) of application, as for
the crops, animals, areas, or
to be treated.

he target pest(s) associated
h site.

e dosage rate associated with
e and pest.

he method of application, in-
instructions for dilution, if re-
and type(s) of application ap-
or equipment required.

he frequency and timing of ap-
s necessary to obtain effective
without causing unreasonable
effects on the environment.

Specific limitations on reentry
where the pesticide has been
meeting the requirements
ing reentry provided by 40
rt 170.

Specific directions concerning
age and disposal of the pesti-
its container, meeting the re-
nts of 40 CFR Part 165. These
ions shall be grouped and
under the heading "Storage
sposal." This heading must be
pe of the same minimum sizes
red for the child hazard warn-
Table in § 162.10(h)(1)(iv).)

y limitations or restrictions on
uired to prevent unreasonable
effects, such as:

equired intervals between ap-
n and harvest of food or feed

otational crop restrictions.

arnings as required against use
ain crops, animals, objects, or
jacent to certain areas.

Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329 Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975; amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

APPENDIX IV-2 (continued)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

Appendix IV-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

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STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

l products are required to bear specific label instructions out storage and disposal. Storage and disposal instructions st be grouped together in the directions for use portion of label under the heading STORAGE AND DISPOSAL. Products tended solely for domestic use need not include the heading TORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading st appear in the minimum type size listed below:

ze of label ront panel in uare inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
and under	6 point
ove 10 to 15	8 point
ove 15 to 30	10 point
er 30.	12 point

rage and disposal instructions must be set apart and arly distinguishable from other directions for use. cking storage and disposal statements with a solid line is gested as a means of increasing their prominence.

Storage Instructions:

product labels are required to have appropriate storage tructions. Specific storage instructions are not prescribed. registrant must develop his own storage instructions, sidering, when applicable, the following factors:

Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

Appendix IV-5
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List) Inert Ingredients:

- Acetone
- Acetonitrile
- Acetophenone
- Acrylic acid
- Aniline
- Benzene
- Chlorobenzene
- Chloroform
- Cyclohexane
- Cyclohexanone
- Dichlorodifluoromethane (Freon 12®)
- Diethyl phthalate
- Dimethylamine
- Dimethyl phthalate
- 1,4-Dioxane
- Ethylene oxide
- Formaldehyde
- Formic acid
- Isobutyl alcohol
- Meleic anhydride
- Methyl alcohol (methanol)
- Methyl ethyl ketone
- Methyl methacrylate
- Naphthalene
- Saccharin and salts
- Thiourea
- Toluene
- 1,1,1-Trichloroethane
- 1,1,2-Trichloroethane
- Trichlorofluoromethane (Freon 11®)
- Vinyl chloride
- Xylene

ATTACHMENT A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

Du-ter Fungicide	05843	(TH)
Du-ter Fungicide	05844	
Du-ter Fungicide PB-47	00160	(UR)
Du-ter Fungicide	00161	
Du-ter Flowable-30	00163	
Du-ter Flowable 640 Fungicide	00164	
Super Tin 4L Guardian Flowable Fungicide	00244	(GR)
Super 16 Sulfur-tin Flowable Fungicide	00252	
Brestan H 47.5 WP Fungicide	00015	(AH)
Du-ter Fungicide	00012	(DU)
TPTH Technical	00013	
Vito Spot Fungicide	00074	(KV)
Ida, Inc. Flo-tin 4L	00014	(ID)
Triple Tin Fungicide	00034	(WI)
Triple Tin 4L	00035	
Vancide KS Industrial Preservative	00037	
Agmark 4-Tin Triphenyltin Hydroxide Flowable Fungicide	00001	(AG)

TH = Thompson-Hayward Chemical Co.: UR = Uniroyal Chemical: GR = Griffin Corporation; AH = American Hoechst Corporation: DU = Duphar, B.V.: KV = Kaw Valley Warehousing Co., Inc.; ID = Ida, Inc.: WI = Wesley Industries Inc.: AG = Agmark

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of the FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient, and type of formulation, such as Manufacturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).

Product Name	%active	Type Formulation	Reg.No.
Du-ter Fungicide	47.5	WP	05843
Du-ter Fungicide	47.5	WP	05844

Registrant: Thompson-Hayward Chemical Company
5200 Speaker Road
Kansas City, KS 66106

Product Name	%active	Type Formulation	Reg.No.
Du-ter Fungicide PB-47	47.5	WP	00160
Du-ter Fungicide	47.5	WP	00161
Du-ter Flowable-30	19.7	FC	00163
Du-ter Flowable 640 Fungicide	40.5	FC	00164

Registrant: Uniroyal Chemical
Division of Uniroyal, Inc.
74 Amity Road
Bethany, CT 06525

Product Name	%active	Type Formulation	Reg.No.
Super Tin 4L Guardian Flowable Fungicide	40.0	FC	00244
Super 16 Sulfur-tin Flowable Fungicide	5.1 (40.9% sulfur)	FC	00252

Registrant: Griffin Corporation
~~ATTN: Linda C. Elliot~~
P.O. Box 1847
Valdosta, GA 31601

Product Name	%active	Type Formulation	Reg.No.
Brestan H 47.5 WP Fungicide	47.5	WP	00015

Registrant: American Hoechst Corporation
Rt 202-206 N.
Summerville, N.J. 08876

Product Name	% active	Type Formulation	Reg.No.
Du-ter Fungicide	47.5	WP	00012
TPTH Technical	96.0	TP	00013
Registrant: Duphar, B.V. ???????? ????????			
Vito Spot Fungicide	47.5	WP	00074
Registrant: Kaw Valley Warehousing Co., Inc. P.O. Box 285 Lansing, KS 66043			
Ida, Inc. Flo-tin 4L	40.0	FC	00014
Registrant: Ida, Inc. Box 9483 2487 Pennsylvania St. Memphis, TN 38109			
Triple Tin Fungicide	47.5	WP	00034
Triple Tin 4L	40.0	FC	00035
Vancide KS Industrial Preservative	95.0	TP	00037
Registrant: Wesley Industries, Inc. P.O. Box 456 Montrose, AL 36559			
Agmark 4-Tin Triphenyltin Hydroxide Flowable Fungicide	40.0	FC	00001
Registrant: Agmark 105 Cherry Creek Dr. Valdosta, GA 31601			